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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional) 48577.2.1																	
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on _____</p> <p>Signature _____</p> <p>Typed or printed name _____</p>		Application Number 10/749,150	Filed December 30, 2003																
		First Named Inventor Marius Filtvedt																	
		Art Unit 3722	Examiner Huong Q. Pham																
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p>																			
<p>I am the</p> <table> <tr> <td><input type="checkbox"/> applicant/inventor.</td> <td><u>Thomas R. Hipkins</u></td> </tr> <tr> <td><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</td> <td><u>Signature</u></td> </tr> <tr> <td><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>57659</u></td> <td><u>Thomas R. Hipkins</u></td> </tr> <tr> <td></td> <td><u>Typed or printed name</u></td> </tr> <tr> <td><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</td> <td><u>(612) 492-7000</u></td> </tr> <tr> <td></td> <td><u>Telephone number</u></td> </tr> <tr> <td></td> <td><u>August 6, 2007</u></td> </tr> <tr> <td></td> <td><u>Date</u></td> </tr> </table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>				<input type="checkbox"/> applicant/inventor.	<u>Thomas R. Hipkins</u>	<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	<u>Signature</u>	<input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>57659</u>	<u>Thomas R. Hipkins</u>		<u>Typed or printed name</u>	<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____	<u>(612) 492-7000</u>		<u>Telephone number</u>		<u>August 6, 2007</u>		<u>Date</u>
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<input type="checkbox"/> *Total of <u>1</u> forms are submitted.																			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Attorney Docket No.: 48577.2.1

Filtvedt, et al.

Application No.: 10/749,150

Examiner: Huong Q. Pham

Filed: December 30, 2003

Group Art Unit: 3743

For: DEVICE FOR APPLYING A PULSATING PRESSURE TO A LOCAL REGION OF THE BODY AND THE APPLICATIONS THEREOF

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REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants are filing a Notice of Appeal and a Pre-Appeal Brief Request for Review concurrently with this document. Applicants submit this document pursuant to the procedures outlined in the PTO's Pre-Appeal Brief Conference Pilot Program. Those procedures require Applicants to "provide a succinct, concise and focused set of arguments for which the review is being requested."

Accordingly, Applicants respectfully request that the Pre-Appeal Brief Review address the three arguments that follow.

**1. The Cited References Do Not Disclose or Teach the Claimed Pulses of Negative Pressure.**

Applicants respectfully dispute that U.S. Patent No. 3,292,613 to MacLeod ("MacLeod") anticipates or renders obvious every combination of negative pressure pulses recited in the currently pending claims.

There are currently 29 claims that recite negative pressure pulses with various combinations of pressure generation and release. Some recite broader or narrower ranges of pressure generation periods, some recite broader or narrower ranges of pressure release periods, and some recite a combination of both.

But the Final Office Action summarily rejects all 29 claims, offering only the following explanations (see pages 4-6):

"MacLeod (3,292,613) teaches 'the pressure can be synchronized to the heart beat or can be applied less or more frequently and in regular multiples of a heart beat , for example , during every second or third heart beat....., or the pressure can be applied irregularly with respect to the heartbeat.' ( column 5, lines 9-20). Therefore, the device of Macleod is capable of providing the recited pressures . Note that the rate of the heartbeat is different from one person to another. While the rate of the heartbeat of one person might be about every second or more, note that the rate of the heartbeat of another person (for example, a person who is sleeping , or in a state of relaxation, or in a meditation state , etc.) might be much longer than one second. Also, note that the device of Macleod is capable of providing the recited pressures.

....

As for claims 29-30, 32-33, 54, 64 –65, 69- 76, note that the claimed time intervals are results of obvious experiments and observations , which are well within the realm of one ordinary skill in the art, and do not provide any unobvious result, and therefore are not patentable over prior art. Note that MacLeod (3,292,613) teaches that " the pressure can be synchronized to the heart beat or can be applied less or more frequently and in regular multiples of a heart beat , for example, during every second or third heart beat....., or the pressure can be applied irregularly with respect to the heartbeat." ( column 5, lines 9-20). Providing this teaching of MacLeod (3,292,613) wherein the pressure can be applied less frequently in regular multiples of a heartbeat ( i.e., in about at least more than one second , or longer), the exact optimum time intervals can be defined by obvious experiments and observations to provide optimum results, which are well within the realm of one ordinary skill in the art, and which do not provide any unexpected results, and therefore is not patentable over prior art."

The claims that recite the broadest ranges of both pressure generation and pressure release recite pressure generation for "between 1 and 20 seconds" and pressure release for "between 2 and 15 seconds." Thus, the shortest claimed pressure pulse is three seconds.

Applicants respectfully submit that MacLeod does not disclose or teach negative pressure pulses that last three seconds, or event that its device is capable of such pulses. In support of their position, Applicants point to several items in the record, including

pages 15-17 and 19-21 of their Response to Office Action dated December 13, 2006; page 15 of their Supplemental Amendment dated February 15, 2007, and the Rule 1.132 Affidavit of Erling Bekkestad Rein. MacLeod's pulses of single-heartbeat duration would last for three seconds only if the heartbeat were 20 beats per minute, which is greatly below average.

Applicants also submit that the Final Office Action's conclusion that the claims reciting narrower ranges of pressure generation and/or release are obvious is contrary to the evidence of record. In support of their position, Applicants point to the same items in the record as are referenced above. Applicants particularly emphasize the evidence found in the Rule 1.132 Affidavit of Erling Bekkestad Rein. That Affidavit explains how the claimed negative pressure pulses were completely unexpected and have generated significant commercial success. Indeed, why would the prestigious *British Journal of Anaesthesia* publish an article related to the claimed pulses more than 50 years after MacLeod's issue date if those pulses were obvious in light of MacLeod. Accordingly, Applicants respectfully submit that the Final Office Action's rejection of the claims reciting combinations of negative pressure generation and release (i.e., claims 1, 19-25, 29-30, 32-33, 48-52, 54, 62, 64-65, and 69-76) should be reversed.

## **2. The Final Office Action Does Not Make a Prima Facie Case Supporting the Rejection of Claim 47.**

The Final Office Action rejects claim 47 as being anticipated by U.S. Patent No. 3,878,839 to Norton ("Norton"), but Applicants respectfully submit that the corresponding explanation does not address every limitation of claim 47's device. Relevant portions of claim 47 are as follows:

a barrier layer of flexible material housed within that chamber for form-fitted engagement against the skin, the barrier layer defining an inner region within the pressure chamber for receiving the limb which is separated from an outer region having a flow of liquid within the chamber,  
wherein the device includes

....  
an element or means for generating a negative pressure between the barrier layer and the area of skin to maintain the barrier layer in contact with the area of skin, *the element or*

*means for generating negative pressure being in communication with the inner region but not with the outer region.*

(emphasis added.) The Final Office Action (page 9) explains its rejection of claim 47 as follows:

"Norton et al teaches a pressure chamber 31 ( figure 6) into which the limb can be inserted, a barrier layer of flexible material 31 housed within that chamber for form-fitted engagement against the skin, the barrier layer defining an inner region within the pressure chamber for receiving the limb which is separated from a flow of liquid within the chamber, wherein the device includes an element or means for generating a pulsating pressure within the pressure chamber, and an element or means for generating a negative pressure between the barrier layer and the area of skin ( figure 14) to maintain the barrier layer in contact with the area of skin. Note column 9, lines 63-68, and column 10, lines 1-21. Therefore, Norton et al 's device is capable of providing the recited pressures ."

As can be seen, this explanation does not address the last limitation recited in claim 47—"the element or means for generating negative pressure being in communication with the inner region but not with the outer region." Thus, the Final Office Action does not make a *prima facie* case supporting the rejection of claim 47. Accordingly, Applicants respectfully submit that the Final Office Action's rejection of claim 47 should be reversed.

### **3. The Final Office Action Does Not Address the Method of Claim 61.**

The Final Office Action likewise rejects claim 61 as being anticipated by Norton, but Applicants respectfully submit that the corresponding explanation bears no relation to claim 61's method. Claim 61 is as follows:

A method of applying a pulsating negative pressure to a local region of the body, comprising:  
providing a pressure chamber containing a gas;  
introducing a limb into the pressure chamber such that the limb is sealed from external conditions;  
partially filling the pressure chamber with a liquid so that the limb is substantially surrounded by and in direct contact with the liquid while leaving a gas pocket above the liquid in an upper region of the chamber;

continuously supplying a constant negative pressure into the gas pocket; and

introducing a positive pressure into the gas pocket for between 2 and 15 seconds to temporarily release negative pressure within the chamber and to temporarily produce a net positive pressure in the gas pocket.

The Final Office Action explains the rejection of claim 61 and claim 47 together. That explanation, found on page 9 of the Final Office Action, is reproduced in section 2 of this document.

As can be seen, the explanation does not address claim 61's method. For example, it does not address claim 61's "continuously supplying" or "introducing" steps. Accordingly, Applicants respectfully submit that the Final Office Action's rejection of claim 61 should be reversed.

### **Conclusion**

In view of the foregoing, Applicants respectfully submit that this application stands in condition for allowance. Applicants respectfully request favorable consideration and prompt allowance. The undersigned invites a telephone conference if deemed useful for any reason.

Respectfully submitted,

Dated:August 7, 2007

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